

### **REMARKS**

Claims 17-19, 21, 22 and 29-34 are pending. Claims 17-19, 21 and 22 stand withdrawn. Claims 29-34 have been rejected. Applicants renew their request that upon allowance of claim 29 that claims 17-19, 21 and 22 be recombined with examined with claims 29-34 and contemporaneously allowed. No claim has been amended or added. Reconsideration is requested.

### **Response to Rejections under 35 USC § 103**

Claims 29- 34 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Esser (U.S. Patent No. 6,096,040) in view of Bailey (U.S. Patent No. 5,607,430). Applicants traverse the rejection for reasons stated below.

Claim 29 in-part recites;

29. An implant plate for stabilizing a fracture, comprising:  
a plate member having an edge defining a head-end portion shaped to bear against a surface of a bone and a shaft-end portion shaped to bear against a surface of a bone, the shaft-end portion being narrower along a lateral direction than the head-end portion []; and  
at least one discrete receiving member protruding from said opposing side surface, located at the head-end portion, and proximate to the edge, each member defining a substantially circular and circumferentially enclosed aperture through which flexible members may be passed through and tightened after the plate member has been secured to the bone surfaces, an edge circumference of each aperture having a distal curved section spaced further from said opposing side surface than a proximal curve section.

Thus claim 29 expressly states that the “at least one discrete receiving member” is on the “head-end portion” and “proximate to the edge.” The PTO admits that while primary reference, *i.e.*, the Esser patent discloses bones plates, Esser does *not* teach or suggest the “at least one discrete receiving member” required by claim 29, or its location and configuration:

... Esser discloses a plate member having an edge defining a head-end portion shaped to bear against a surface of a bone and a shaft-end

portion shaped to bear against a surface of a bone (Figures 3-5 and column 5, lines 52-64), the shaft-end portion being narrower along a lateral direction than the head-end portion (Figure 3) [ ] Esser does not disclose at least one discrete receiving member protruding from the opposing side surface, located at the head-end portion, and proximate to the edge, each member defining a substantially circular and circumferentially enclosed aperture through which flexible members may be passed through and tightened after the plate member has been secured to the bone surfaces, an edge circumference of each aperture having a distal curved section spaced further from the opposing side surface than a proximal curve section. (Emphasis added) (Amdt., page 3).

To remedy the admitted deficiency, the PTO relies on the teachings of the Bailey patent, and in particular Bailey's integral boss 18:

Bailey does teach at least one discrete receiving member protruding from the opposing side surface (Figure 1, boss 18) . . . (Id.)

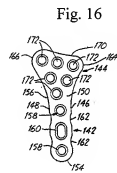
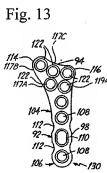
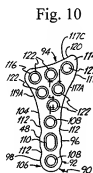
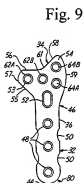
The PTO concludes it is obvious to add boss 18 of Bailey to the bone plates of Esser:

It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the "bosses" for holding a cable in place to further secure a bone plate as disclosed in Bailey with the shape and configuration of the bone plate for use with long bones as disclosed in Esser. The adaption of bosses to hold cabling and further secure a bone plate is applicable to any bone plate where additional fixation support would be beneficial. (Amdt. Pages 3-4).

The Esser patent discloses a humerus bone plate that includes an elongated shaft section 32 and an enlarged head section 34 that would respectively engage humerus shaft 15 and humerus head 4 (6/38-55).<sup>1</sup> See below:



Esser contemplates other designs, illustrated below, but in each case the bone plate has an enlarged head section designed to engage the head of a bone and a narrower shaft section to engage the bone shaft.



Esser also discloses the head section is specifically configured for the proximal head of the bone, e.g., the “head of the proximal humerus,” illustrated and disclosed to have complex geometry (Abstract):

<sup>1</sup> The notation (6/38-55) denotes column and line number of the reference.

The head portion includes a first head section (53) and a second head section (54), with an obtuse angle defined therebetween. The first and second head sections (53, 54) extend laterally away from a longitudinal axis of the shaft portion (32) in generally opposite directions. The second head section (54) is configured and arranged with lateral portion (86) to secure multiple fractures of a head of proximal humerus while extending laterally adjacent to the biceps tendon to preserve the tendon. First head section (53) forms an angled gap (61) relative to second head section (54) to avoiding impingement of the acromion process of the shoulder.

The head sections disclosed by Esser are unsymmetrical in design, and have both longitudinally and laterally arranged plate holes. Head plate sections include at least three laterally arranged plate holes and fasteners that would implicitly minimize undesired lateral shifting of a plate that could occur with a single, axial, row of plate holes and fasteners, a problem more prevalent with the axial type fastening arrangement Bailey is attempting to improve.

The laterally arranged plate holes, when combined with the longitudinally arranged plate holes in Esser, should render Esser's bone plate unsusceptible to the lateral or longitudinal shifting problem likely to occur with a single, axial, row of plate holes and fasteners. Thus, at least the geometry and plate hole arrangement of Esser head section would appear to discourage the inclusion of any addition fastening mechanisms, absent a recognition in the art that Esser's fastening technique is deficient or defective. The PTO has not provided any evidence to support such a conclusion, or warrant any supplemental fastening at the head section.

More importantly, the Bailey patent does not appear to support the modification suggested by the PTO office Action. Bailey discloses it is desirable to make bosses 18 (or bosses 518 / 618) an integral part of the plate (5/14-16), and that the bosses are designed to make sure the wire is in continuous surface contact with the plate (5/8-13):

It has been found that by providing a continuous cable contact surface, the stresses in cable 21 are more evenly distributed throughout the cable rather than being concentrated at certain points. This stress distribution strategy is further accomplished by contouring the outer surface 14 so that it is tangent to the cylindrical surface defining holes 22 at its ends 24.

Bosses 18 of Bailey include holes 22, 122 that respectively open proximal to opposite plate edges. Bailey illustrates the use of the boss 18 on plate sections that engage the shaft or narrow portion of a bone which is not configured for laterally arranged fasteners. For example, Figure 1 appears to illustrate a bone plate of uniform dimension that is juxtaposed against a bone shaft. With respect to Figures 10 and 11, bosses 518 /618 are only located on the shaft portion of the plate.

Fig. 1.

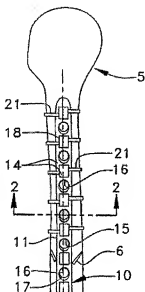


Fig. 10

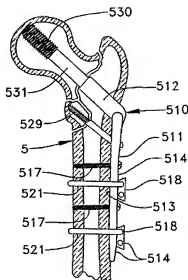
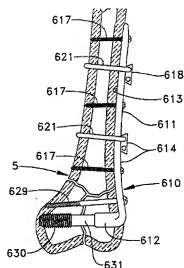


Fig. 11



Thus, Bailey would appear to teach away from using bosses 18 on head sections of bone plates. In re Icon Health & Fitness, Inc., 496 F.3d 1374, 1381 (Fed. Cir. 2007) (“A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant;” citing In re Gurley, 27 F.3d 551, 553 (Fed. Cir. 1994); See KSR Int’l Co. v. Teleflex Inc. et al., 127 S.Ct. 1727, 1740 (April 30, 2007) (explaining that when the prior art teaches away from a combination, that combination is more likely to be nonobvious).

In addition, bosses 18 are illustrated to be centrally located, and span a substantial width of the plate. The head sections, as illustrated by Esser, are unsymmetrical in design, and have longitudinally located plate holes and laterally located plate holes, the latter implicitly minimizing undesired lateral shifting of the plate that would be prevalent in the axial type fastening arrangements Bailey is attempting to improve. Locating such structure on the head portion of the Esser plate would appear problematic, and neither Bailey nor the PTO has provided any details as to how such a modification should be made. Clearly, any fastener rearrangement of Esser's plates to provide a space for the "boss 18" would require an impermissible redesign. In re Ratti, 270 F.2d 810, 812 (CCPA 1959) (Improper redesign and altering attachment principles of the prior art to arrive at the claimed invention).

It is unclear where and why one of ordinary skill in the art would desire to add the Bailey bosses to the head section of the Esser plate in view of its complex geometry and plate hole construction. The PTO office action does not provide any guidance in this regard other than Bailey teaches what the PTO construes as Applicants' receiving member. There is clearly no sufficient articulated reason to justify the suggested modification. KSR, 127 S.Ct. at 1739–1741:

[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness).

**Conclusion**

For reasons given above, the rejection of claims 29, 31-32, and 34 is improper and should be withdrawn. Claims 30 and 33 both depends from claim 29, and are allowable for the same reasons. Accordingly, in view of the above amendments, Applicants submit that the present application is in condition for allowance.

**Authorization**

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1073, under Order No. A8130.0659/P659.

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